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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,520	12/14/2001	Gene Parunak	10255-018-999	3929

7590 05/19/2004

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EXAMINER	
SINES, BRIAN J	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,520	PARUNAK ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/6/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *34 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 1 – 33, in the response filed 4/6/2004 is acknowledged.

Claims 34 and 35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "enrichment channel" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitation "liquid" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

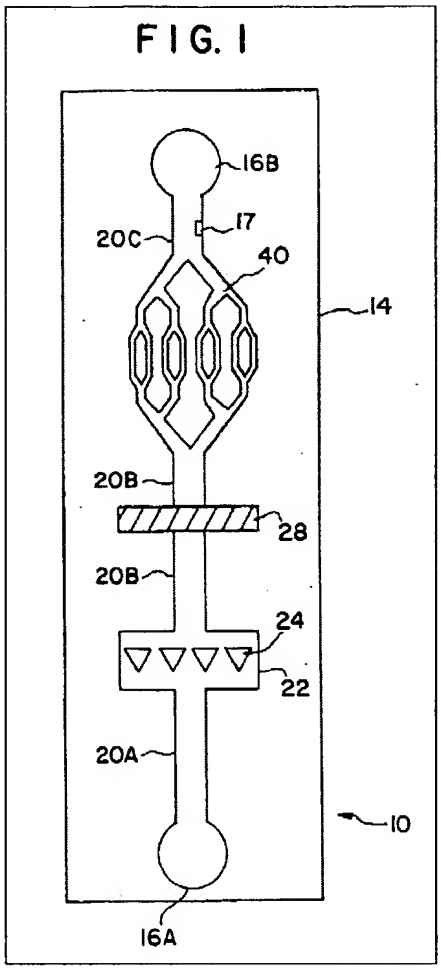
The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

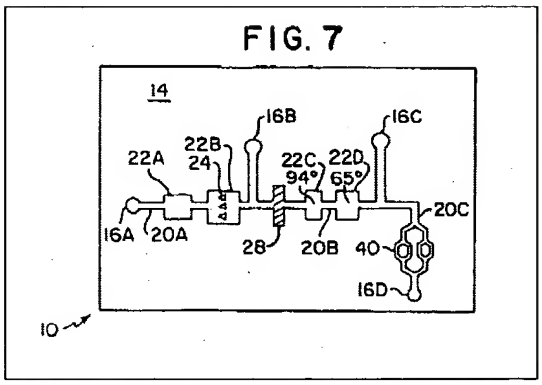
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1 – 13, 16, 18 – 30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. (U.S. Pat. No. 5,635,358 A) in view of Brody (U.S. Pat. No. 5,726,404 A). Regarding claims 1 and 19, Wilding et al. teach a microfluidic apparatus comprising an enrichment zone (e.g., sections 22C & 22D) and a fluid flow control system incorporating the use of pumps (see col. 10, lines 44 – 62; col. 8, lines 52 – 66; figures 1 & 7). Wilding et al. do not specifically teach the incorporation of a gas actuator system for providing fluid flow control. However, gas actuated fluid flow control systems for microfluidic devices are well known in the art, as is evidenced by Brody (see col. 4, lines 32 – 67; col. 6, lines 57 – 60). Hence, these fluid flow mechanisms are considered functional equivalents recognized in the

prior art (see MPEP 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, a person of ordinary skill in the art would have recognized the suitability of using a gas actuated mechanism within a microfluidic apparatus for the same intended purpose of facilitating sample fluid flow control within the microfluidic apparatus (see MPEP § 2144.07). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a gas actuated pumping mechanism to facilitate sample fluid movement, as taught by Brody, with the Wilding et al. microfluidic apparatus, in order to facilitate effective sample fluid transfer and processing within the apparatus.





Regarding claims 2, 3, 20 and 21, Wilding et al. teach the incorporation of a flow through or partition member comprising a filter (28) (see figures 1 & 7). Regarding claims 4 and 22, Wilding et al. teach the incorporation of a downstream region (e.g., fractal detection region

40) (see col. 9, lines 1 – 5). Regarding claims 5 – 7, 23 and 24, Wilding et al. teach the incorporation of valves to control fluid flow within the apparatus, such as through ports 16C and 16D (see col. 10, lines 10 – 67). In addition, with respect to the functional recitations of claims 7, 24 and 26, the applicant is advised that the Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

Regarding claims 8, 10, 25 and 33, Wilding et al. teach that each of the components (i.e., mesoscale flow channel 20, cell lysis chamber 22, and fractal detection region 40, etc.) of the microfluidic apparatus are integral to a silicon substrate (14) (see col. 8, lines 52 – 66; figures 1 & 2). Furthermore, the Courts have held that the use of a one-piece, integrated construction instead of the structure disclosed in the prior art would have been within the ambit of a person of ordinary skill in the art. See *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). Therefore, it would have been obvious to a person of ordinary skill in the art to integrate each of the functional components of the microfluidic apparatus within a silicon substrate.

Regarding claim 9, this claim recites a functional limitation attributed to the gas actuator of the microfluidic apparatus, as taught by Wilding et al. in view of Brody. The applicant is advised that the Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the

structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

Regarding claim 11, Wilding et al. teach the incorporation of a mixing zone (section 22D) (see col. 10, lines 44 – 62; figure 7).

Regarding claims 12, 13 and 27 – 29, the applicant is advised that these claims recite process or intended use limitations (i.e., what is processed by the claimed apparatus, such as the particle sample or liquid), which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited process or use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentablility to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

Regarding claims 16 and 32, Wilding et al. teach that the apparatus is utilized in performing PCR (see col. 1, lines 19 – 33; col. 10, lines 10 – 62).

Regarding claim 18, Wilding et al. teach a fluid source channel (e.g., 20A, 16A) in fluid communication with the enrichment zone (22) (see figure 1).

Regarding claim 30, Wilding et al. teach the incorporation of a positioning element for lysing (24) in lysing zone (22) (see figure 1).

2. Claims 14, 15, 17 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. and Brody, as applied to claims 1 – 13, 16, 18 – 30, 32 and 33 above, and further in view of Tai et al. (U.S. Pat. No. 6,534,295 B2). Wilding et al. do teach the incorporation of a lysing zone (cell handling region 22) (see col. 6, lines 30 – 49; figure 1). Wilding et al. and Brody do not specifically teach the incorporation of an electrical field-based cell lysing mechanism within the microfluidic apparatus or a method step employing the use of such a lysing mechanism. However, Tai et al. do teach a micromachined cell lysis device based upon the application of pulsed electric fields (see col. 2, lines 31 – 67). Both of the cell lysing mechanisms disclosed by Wilding et al. and Tai et al. are notoriously well known in the art for being utilized for the same intended purpose, for the lysis of cell-containing samples within microfluidic devices. Hence, these cell lysis mechanisms are considered functional equivalents clearly recognized in the prior art (see MPEP 2144.06). Therefore, a person of ordinary skill in the art would have recognized the suitability of using an electrode-based cell lysis device within a microfluidic apparatus for the same intended purpose of facilitating cell lysis (see MPEP § 2144.07). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In*

re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the teachings of Tai et al. regarding the use of a micromachined electrical field-based cell lysis device with the Wilding et al. microfluidic apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to provide a micromachined electric field-based cell lysing mechanism, as taught by Tai et al., with the microfluidic apparatus of Wilding et al. and Brody in order to facilitate effective cell lysing and subsequent analysis. Regarding claim 15, Wilding et al. teach the use of a positioning element, such as a pump, for effecting fluid transfer through the microfluidic device (see col. 8, lines 46 – 66; col. 9, lines 6 – 23).

Regarding claim 17, Wilding et al. teach that each of the functional components (i.e., mesoscale flow channel 20, cell lysis chamber 22, and fractal detection region 40, etc.) of the microfluidic apparatus are integral to a silicon substrate (14) (see col. 8, lines 52 – 66; figures 1 & 2). Furthermore, the Courts have held that the use of a one-piece, integrated construction instead of the structure disclosed in the prior art would have been within the ambit of a person of ordinary skill in the art. See *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). Therefore, it would have been obvious to a person of ordinary skill in the art to integrate each of the functional components of the microfluidic apparatus within a silicon substrate.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Briscoe et al. teach a microfluidic DNA analysis apparatus. Anderson et al. teach an integrated nucleic acid diagnostic device. Nelson et al. teach an integrated microfluidic device, which incorporates the use of an enrichment channel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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